

Complete Summary

GUIDELINE TITLE

Antithrombotic therapy in patients with saphenous vein and internal mammary artery bypass grafts. In: Sixth ACCP Consensus Conference on Antithrombotic Therapy.

BIBLIOGRAPHIC SOURCE(S)

Stein PD, Dalen JE, Goldman S, Theroux P. Antithrombotic therapy in patients with saphenous vein and internal mammary artery bypass grafts. Chest 2001 Jan; 119(1 Suppl): 278S-282S. [42 references]

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Coronary artery disease: saphenous vein and internal mammary artery bypass grafts

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To review the literature on the effects of treatment with antithrombotic agents on the patency of saphenous vein bypass grafts and internal mammary artery bypass grafts
- To make evidence-based recommendations on the treatment of saphenous vein bypass grafts and internal mammary artery bypass grafts with antithrombotic agents for the purpose of maintaining graft patency

TARGET POPULATION

Patients who have undergone saphenous vein and internal mammary artery bypass graft procedures for coronary artery disease

INTERVENTIONS AND PRACTICES CONSIDERED

Treatment

1. Aspirin therapy
2. Clopidogrel, as an alternative to aspirin therapy
3. Oral anticoagulants
4. Aspirin therapy in combination with oral anticoagulants

Note: The following medications, or combinations of medications were considered but not recommended: aspirin in combination with dipyridamole, indobufen, ticlopidine, sulfinpyrazone.

MAJOR OUTCOMES CONSIDERED

- Efficacy of treatment on graft patency
- Rates of bleeding complications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The participants reviewed information from an exhaustive review of the literature.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The rating scheme framework captures the trade-off between benefits and risks (1 or 2) (see "Rating Scheme for the Strength of the Recommendations") and the methodologic quality of the underlying evidence (A, B, C+, or C).

Grades of evidence for antithrombotic agents:

1A

Methodological strength of supporting evidence: randomized controlled trials without important limitations

1B

Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)

1C+

Methodological strength of supporting evidence: no randomized controlled trials, but randomized controlled trial results can be unequivocally extrapolated; or, overwhelming evidence from observational studies

1C

Methodological strength of supporting evidence: observation studies

2A

Methodological strength of supporting evidence: randomized controlled trials without important limitations

2B

Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)

2C

Methodological strength of supporting evidence: observational studies

* Such situations include randomized controlled trials with lack of blinding, and subjective outcomes, in which the risk of bias in measurement of outcomes is high; and randomized controlled trials with large loss to follow-up.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The strength of any recommendation depends on two factors: the trade-off between benefits and risks, and the strength of the methodology that leads to estimates of the treatment effect. The rating scheme used for this guideline captures these factors. The guideline developers grade the trade-off between benefits and risks in two categories: (1) the trade-off is clear enough that most patients, despite differences in values, would make the same choice; and (2) the trade-off is less clear, and each patient's values will likely lead to different choices.

When randomized trials provide precise estimates suggesting large treatment effects, and risks and costs of therapy are small, treatment for average patients with compatible values and preferences can be confidently recommended.

If the balance between benefits and risks is uncertain, methodologically rigorous studies providing grade A evidence and recommendations may still be weak (grade 2). Uncertainty may come from less precise estimates of benefit, harm, or costs, or from small effect sizes.

There is an independent impact of validity/consistency and the balance of positive and negative impacts of treatment on the strength of recommendations. In situations when there is doubt about the value of the trade-off, any recommendation will be weaker, moving from grade 1 to grade 2.

Grade 1 recommendations can only be made when there are precise estimates of both benefit and harm, and the balance between the two clearly favors recommending or not recommending the intervention for the average patient with compatible values and preferences. Table 2 of the original guideline document summarizes how a number of factors can reduce the strength of a recommendation, moving it from grade 1 to grade 2. Uncertainty about a recommendation to treat may be introduced if the target event that is trying to be prevented is less important (confident recommendations are more likely to be made to prevent death or stroke than asymptomatic deep venous thrombosis); if the magnitude of risk reduction in the overall group is small; if the risk is low in a particular subgroup of patients; if the estimate of the treatment effect, reflected in a wide confidence interval (CI) around the effect, is imprecise; if there is substantial potential harm associated with therapy; or if there is an expectation for a wide divergence in values even among average or typical patients. Higher costs would also lead to weaker recommendations to treat.

The more balanced the trade-off between benefits and risks, the greater the influence of individual patient values in decision making. If they understand the benefits and risks, virtually all patients will take aspirin after myocardial infarction

or will comply with prophylaxis to reduce thromboembolism after hip replacement. Thus, one way of thinking about a grade 1 recommendation is that variability in patient values or individual physician values is unlikely to influence treatment choice in average or typical patients.

When the trade-off between benefits and risks is less clear, individual patient values will influence treatment decisions even among patients with average or typical preferences.

Grade 2 recommendations are those in which variation in patient values or individual physician values will often mandate different treatment choices, even among average or typical patients.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The rating scheme framework captures the trade-off between benefits and risks (1 or 2) and the methodologic quality of the underlying evidence (A, B, C+, or C) (see "Rating Scheme for the Strength of the Evidence").

Grades of recommendation for antithrombotic agents:

1A

Clarity of risk/benefit: risk/benefit clear

Implications: strong recommendation; can apply to most circumstances, without reservation

1B

Clarity of risk/benefit: risk/benefit clear

Implications: strong recommendation; likely to apply to most patients

1C+

Clarity of risk/benefit: risk/benefit clear

Implications: strong recommendation; can apply to most patients in most circumstances

1C

Clarity of risk/benefit: risk/benefit clear

Implications: intermediate-strength recommendation; may change when stronger evidence available

2A

Clarity of risk/benefit: risk/benefit unclear

Implications: intermediate strength recommendation; best action may differ, depending on circumstances or patients' societal values

2B

Clarity of risk/benefit: risk/benefit unclear

Implications: weak recommendation; alternative approaches likely to be better for some patients under some circumstances

2C

Clarity of risk/benefit: risk/benefit unclear

Implications: very weak recommendation; other alternatives may be equally reasonable

COST ANALYSIS

While the American College of Chest Physicians conference participants considered cost in deciding on the strength of recommendations, the paucity of rigorous cost-effective analyses and the wide variability of costs across jurisdictions led the guideline developers to take a conservative approach to cost issues. That is, cost considerations influenced the recommendations and the grades of those recommendations only when the gradient between alternatives was very large.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The initial guidelines were prepared by the chapter committee (the primary authors) and then reviewed separately by the Committee Co-Chairs and methodology experts and finally by the entire group of Consensus Guideline participants.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Please note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Excerpted by the National Guideline Clearinghouse (NGC):

The grading scheme is defined at the end of the Major Recommendations.

Saphenous Vein Bypass Grafting

1. For patients who undergo saphenous vein bypass grafting for coronary artery disease, the guideline developers recommend life-long aspirin therapy (grade 1A). The guideline developers recommend aspirin therapy, 325 mg/day, starting 6 hours after operation for 1 year to reduce the frequency of saphenous vein bypass graft closure (grade 1A).
2. If bleeding prevents the administration of aspirin at 6 hours after surgery, the guideline developers recommend starting aspirin therapy as soon as possible thereafter (grade 1C+).
3. For patients allergic to aspirin, the guideline developers recommend clopidogrel, 300 mg, as a loading dose 6 hours after operation followed by 50 to 100 mg daily by mouth (grade 2C).

4. The guideline developers recommend that oral anticoagulants alone or in combination with aspirin should be considered after coronary artery bypass surgery in patients in whom oral anticoagulants are simultaneously indicated, for example, because of heart valve replacement (grade 2C).

Internal Mammary Artery Bypass Grafting

1. For patients who undergo internal mammary artery bypass grafting for coronary artery disease, the guideline developers recommend life-long aspirin therapy (grade 1A). Aspirin has not been shown to be beneficial in maintaining internal mammary artery bypass graft patency, and the guideline developers do not recommend aspirin if other diagnoses prompted internal mammary artery bypass grafting (grade 2C).

The rating scheme framework captures the trade-off between benefits and risks (1 or 2) and the methodologic quality of the underlying evidence (A, B, C+, or C).

Definitions:

Grades of recommendations:

1A

Clarity of risk/benefit: risk/benefit clear

Methodological strength of supporting evidence: randomized controlled trials without important limitations

Implications: strong recommendation; can apply to most circumstances, without reservation

1B

Clarity of risk/benefit: risk/benefit clear

Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)

Implications: strong recommendation; likely to apply to most patients

1C+

Clarity of risk/benefit: risk/benefit clear

Methodological strength of supporting evidence: no randomized controlled trials, but randomized controlled trial results can be unequivocally extrapolated; or, overwhelming evidence from observational studies

Implications: strong recommendation; can apply to most patients in most circumstances

1C

Clarity of risk/benefit: risk/benefit clear

Methodological strength of supporting evidence: observation studies

Implications: intermediate-strength recommendation; may change when stronger evidence available

2A

Clarity of risk/benefit: risk/benefit unclear

Methodological strength of supporting evidence: randomized controlled trials without important limitations

Implications: intermediate strength recommendation; best action may differ, depending on circumstances or patients' societal values

2B

Clarity of risk/benefit: risk/benefit unclear

Methodological strength of supporting evidence: randomized controlled trials with important limitations (inconsistent results, methodologic flaws*)

Implications: weak recommendation; alternative approaches likely to be better for some patients under some circumstances

2C

Clarity of risk/benefit: risk/benefit unclear

Methodological strength of supporting evidence: observational studies

Implications: very weak recommendation; other alternatives may be equally reasonable

* Such situations include randomized controlled trials with lack of blinding, and subjective outcomes, in which the risk of bias in measurement of outcomes is high; and randomized controlled trials with large loss to follow-up.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (refer to "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Antithrombotic therapy has the potential for improving patency rates in saphenous vein bypass grafts, and thus preventing vein graft occlusion.

POTENTIAL HARMS

Bleeding is the primary complication of antithrombotic therapy in patients with saphenous vein bypass grafts.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Interpreting the Recommendations

The authors of these guidelines offer recommendations that should not be construed as dictates by the readers, including clinicians, third-party payers, institutional review committees, and courts. In general, anything other than a 1A recommendation indicates that the chapter authors acknowledge that other interpretations of the evidence and other clinical policies may be reasonable and appropriate. Even grade 1A recommendations will not apply to all circumstances and all patients. For instance, the guideline developers have been conservative in their considerations of cost, and have seldom downgraded recommendations from 1 to 2 on the basis of expense. As a result, in jurisdictions in which resource constraints are severe, alternative allocations may serve the health of the public far more than some of the interventions that the developers designate grade 1A. This will likely be true for all less-industrialized countries. However, a weak recommendation (2C) that reduces resource consumption may be more strongly indicated in less-industrialized countries.

Similarly, following grade 1A recommendations will at times not serve the best interests of patients with atypical values or preferences. For instance, consider patients who find anticoagulant therapy extremely aversive, either because it interferes with their lifestyle (prevents participation in contact sports, for instance) or because of the need for monitoring. For such patients, clinicians may reasonably conclude that following some grade 1A recommendations for anticoagulation will be a mistake. The same may be true for patients with particular comorbidities (such as a recent gastrointestinal bleed or a balance disorder with repeated falls) or other special circumstances (such as very advanced age).

The guideline developers trust that these observations convey their acknowledgment that no guidelines or recommendations can take into account the often compelling idiosyncrasies of individual clinical circumstances. No clinician and no one charged with evaluating the actions of a clinician should attempt to apply their recommendations in a rote or blanket fashion.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Stein PD, Dalen JE, Goldman S, Theroux P. Antithrombotic therapy in patients with saphenous vein and internal mammary artery bypass grafts. Chest 2001 Jan; 119(1 Suppl): 278S-282S. [42 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jan

GUIDELINE DEVELOPER(S)

American College of Chest Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

Funding was supplied by DuPont Pharmaceuticals.

GUIDELINE COMMITTEE

American College of Chest Physicians Consensus Panel on Antithrombotic Therapy

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Paul D. Stein, MD, FCCP, Chairman; James E. Dalen, MD, FCCP; Steven Goldman, MD; Pierre Theroux, MD.

Committee Co-Chairs: James E. Dalen, MD, MPH, FCCP; Jack Hirsh, MD, FCCP.

Participants: Giancarlo Agnelli, MD; Gregory W. Albers, MD; Joseph S. Alpert, MD, FCCP; Pierre Amarenco, MD; Sonia S. Anand, MD; David Anderson, MD; Frederick A. Anderson, PhD; Maureen Andrew, MD; Jack E. Ansell, MD; Peter B. Berger, MD; Edward Bovill, MD; Heiner Bucher, MD, MPH; Henry I. Bussey, PharmD; Christopher P. Cannon, MD; John Cairns, MD; G. Patrick Clagett, MD; Clifford W. Colwell, Jr., MD; Barry S. Collier, MD; Deborah J. Cook, MD, MSc, FCCP; Mark Crowther, MD; Denise Hartnett Daudelin, RN, MPH; Daniel Deykin, MD; J. Donald Easton, MD; Mark H. Eckman, MD; Michael Ezekowitz, MD; Garrett FitzGerald, MD; Valentin Fuster, MD; William Geerts, MD, FCCP; Michael Gent, DSc; Jeffrey S. Ginsberg, MD, FCCP; Steve Goldman, MD; Christopher Granger, MD; Ian A. Greer, MD; Gordon H. Guyatt, MD; Jonathan L. Halperin, MD; Robert A. Harrington, MD;

John Heit, MD; Russell D. Hull, MBBS, FCCP; Thomas M. Hyers, MD, FCCP; Mark R. Jackson, MD; Alan K. Jacobson, MD; Roman Jaeschke, MD, MSc, Clive Kearon, MB, PhD, FCCP; J. Ward Kennedy, MD; Seth Landefeld, MD; Mark N. Levine, MD; Herbert J. Levine, MD; H Daniel Lewis, Jr., MD; A. Michael Lincoff, MD; David Matchar, MD; Kevin M. McIntyre, MD, JD; Thomas W. Meade, DM, Alan D. Michelson, MD; Paul Monagle, MBBS; Timothy A. Morris, MD; E. Magnus Ohman, MD, FCCP; Guy Paiement, MD; Carlo Patrono, MD; Stephen G. Pauker, MD; Palle Petersen, MD, DMSc; Graham Frederick Pineo, MD Leon Poller, DSc, MD; Jeffrey J. Popma, MD; Robert Raschke, MD, MS; Gary Raskob, PhD; Joshua Riff; Gerald Roth, MD; Ralph L. Sacco, MD; Eduardo Salazar, MD; Deeb N. Salem, MD, FCCP; Michel M. Samama, MD; Holger J. Schunemann, MD, MSc; Stephen G. Shaughnessy, PhD; Daniel Singer, MD; Paul D. Stein, MD, FCCP; Victor F. Tapson, MD, FCCP; Philip Teal, MD; Pierre Theroux, MD; Alexander G. G. Turpie, MD; Ted Warkentin, MD; John G. Weg, MD, FCCP; Jeffrey Weitz, MD; H. Brownell Wheeler, MD.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

Please note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

GUIDELINE AVAILABILITY

Electronic copies of the updated guideline: Available from the [Chest - The Cardiopulmonary and Critical Care Journal Web site](#).

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Sixth ACCP Consensus Conference on Antithrombotic Therapy (2001): quick reference guide for clinicians. Northbrook, IL: ACCP, 2001.

Electronic copies: Available in from the [American College of Chest Physicians Web site](#). (Downloadable files intended for use with Palm OS compatible devices are available.)

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348, or by calling 1 (800) 343-2227.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on July 30, 2001. The information was verified by the guideline developer on September 27, 2001.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which may be subject to the guideline developer's copyright restrictions.

© 1998-2004 National Guideline Clearinghouse

Date Modified: 11/8/2004

The logo for FIRSTGOV, with "FIRST" in blue and "GOV" in red, and a small red star above the "I".

